DISPOSITION: On 2-9-59, the case came to trial before a jury and was terminated by a verdict of guilty. On 2-16-59, the court imposed a \$200 fine, and the defendant was given a 6 month suspended jail sentence and placed on probation for 3 years.

5700. (F.D.C. No. 41753. S. Nos. 53-883/4 M, 53-886/7 M, 53-889 M.)

INFORMATION FILED: 4-22-59, S. Dist. Tex., against Seymour J. Sanov, t/a MacGregor Pharmacy, Houston, Tex.

CHARGE: Between 5-3-57 and 5-9-57, Equanil tablets were dispensed twice and Meticorten tablets, and Gantrisin tablets were each dispensed once without a prescription, and penicillin tablets were dispensed once upon request for a prescription refill without authorization from a prescriber.

PLEA: Not guilty.

DISPOSITION: On 7-8-59, the case came to trial before the court without a jury and at the conclusion of the trial the defendant was found guilty. On 7-20-59, the defendant was fined \$250.

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^{1 (5695, 5697-5700)} Prosecution contested.

^{2 (5680)} Prosecution contested. Contains opinion of the court.

D.D.N.J., F.D.C. 5701-5741



U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5701-5740

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) criminal proceedings terminated with a plea of guilty or nolo contendere; and (3) an injunction proceeding terminated with a dismissal after the granting of a temporary restraining order. The seizure proceedings are civil actions taken against the goods alleged to be in violation, and the criminal and injunction proceedings are against the firms or individuals charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, Commissioner of Food and Drugs. Washington, D.C., February 26, 1960.

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For presence of a habit-forming substance without warning statements, see No. 5707; omission of, or unsatisfactory, ingredient statements, Nos. 5705, 5707, 5709, 5716; an imitation of, and sale under name of, another drug, No. 5705; failure to bear a label containing an accurate statement of the quantity of the contents; Nos. 5705, 5707, 5709, 5716; failure to bear a label containing the name and place of business of the manufacturer, packer; or distributor, Nos. 5705, 5707, 5716; cosmetic, actionable under the drug previsions of the Act, No. 5712.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5701-5740

Adulteration, Section 501(a)(1), the article consisted in part of a filthy substance; Section 501(a)(2), the article had been prepared, packed, or held under insanitary conditions; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary) and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading: Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; and (3) the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and Section 503(b)(4), the article was subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and, in another case, the article bore the caution statement quoted above, but the article was not one to which Section 503(b)(1) applies.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5701. Vitamin capsules. (F.D.C. No. 41851. S. No. 35-361 P.)

QUANTITY: 171 btls. at Philadelphia, Pa.

701

SHIPPED: The capsules were shipped in bulk, on 3-19-58, from Detroit, Mich.

LABEL IN PART: (Btl.) "500 Capsules List No. 100 VITAL B-C THERAPEUTIC FORMULA Each capsule contains 25,000 units of Vitamin A * * *

1 mg. of Vitamin B₁ * * 5 mg. Ascorbic Acid * * * Prepared for Daniel Cooperman."

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